

## REMARKS

Reconsideration of this Application is respectfully requested. Claims 1-70 are pending; claims 16, 18, and 19 are currently amended; claims 5, 8, 17, 20-22, 30, 38, 45, 65 and 66 are canceled; no claims are original; no claims are previously presented; claims 67-70 are new; and claims 1-4, 6, 7, 9-15, 23-29, 31-37, 39-44, and 46-64 are withdrawn. No new matter is added by the claim amendments. The Remarks below are directed to the rejections of the outstanding Office Action.

The Owner of the application thanks Examiners Prouty and Walicka for the Telephone Interviews of 18 and 22 August 2003 and for their thoughtful input.

Numerous amendments to the specification have been made to ensure that all references to sequences include a sequence identification number. In addition, other minor amendments have been made to the specification and drawings to clarify the nature of the splice variants. These amendments are being made in the sister case 09/502,424 in response to objections by the Examiner. The same amendments are being made here for consistency between the applications. The amendments largely consist of adding SEQ ID Nos: to the text. No new matter is added by these amendments.

### Remarks to Rejections

*Rejection (item 1.1):* The Examiner has rejected claims 18, 65 and 66 under 35 U.S.C. §112, second paragraph, for indefiniteness. In particular, the Examiner rejected claim 18, and its dependent claims 65 and 66 as confusing on the basis that it appears to be broader than claim 16 from which it depends.

*Remarks:* This rejection has been obviated by cancellation of claims 65 and 66 and amendment of claim 18 to remove the confusing language. Therefore, the Examiner is respectfully requested to withdraw this rejection.

*Rejection (item 1.2):* Claim 16 and its dependent claims 18-19, 22 and 65-66 were rejected under 35 U.S.C. §112, first paragraph, for lack of written description. In essence, the Examiner believes that the disclosure does not sufficiently describe the genus of isolated proteins that comprise a splice variant of any human telomerase gene or a protein comprising them.

*Remarks:* The Owner respectfully but strongly disagrees with the Examiner's

assertion that the genus claimed in claim 16 lacks sufficient description because the specification does not contain disclosure of the structure and function of all proteins comprising a splice variant of human telomerase (OA at page 4). The reasons for disagreement have been put forth in previous amendments and are only briefly iterated here.

As the Examiner herself points out, the inventors provide the “amino acid structure and function encoded by many splice variants of SEQ ID NO:1” (OA at page 4). The written description requirement does not require that each and every species of a genus be disclosed to the level of its primary nucleotide or amino acid sequence. The proper test for adequate written description is whether one of skill in the art would understand, from reading the description, whether the inventors had possession of the subject matter of the claims. One of skill in the art can distinguish the claimed sequences from any other sequence and can identify many if not all of the species that the claims encompass. Thus, the claims satisfy the written description requirement as enunciated in *Eli Lilly*. Specifically, the genus in the claims are very well defined in that all of the proteins encompassed by the claimed genus are well-defined as specifically enumerated splice variants of a reference human telomerase sequence. A person skilled in the art would be able to distinguish any protein species of the claimed genus by comparison with the sequence of the reference human telomerase protein.

In order to advance prosecution, however, Claim 16 has been amended in accordance with the suggestion by the Examiner in the OA at page 5. In addition, new claim 70 recites a more defined genus of splice variant proteins. Furthermore, the identification of a splice variant is clarified as excluding SEQ ID No: 2, which is the reference telomerase protein. Support that SEQ ID No: 2 is a reference protein may be found in the specification in the paragraph bridging pages 11 and 12, the first full paragraph on page 20, and Figure 11D, among other places.

As the rejection applies to claim 19, which is directed to fragments of the splice variants, the Owner asserts that the claim satisfies the written description requirement. Because the claim recites specific fragments and the claim language is “closed”, the structure of the claimed fragments is well defined. One of skill in the art can readily distinguish the claimed sequences from any other sequence and can identify all of the species that the claims encompass.

Similarly, new claims 67-69 satisfy the written description requirement. The

structure of the claimed sequences is provided in the specification. Contemplation of sequences related by 90% amino acid identity is presented on pages 8 and 9 of the specification. The proteins are further related by functional criteria, namely that the variants bind telomerase RNA and are not SEQ ID No: 2, the reference human telomerase protein. The fragments of claim 69 derive support from Example 8 of the instant specification. SEQ ID No: 44 is a human telomerase splice variant with an alternate C-terminus. The sequence is presented as Figure 11H. Thus, the claim recites sequences that one of skill in the art can readily distinguish from any other sequence as well as identify all or nearly all of the species that the claims encompass. Therefore, withdrawal of this rejection is respectfully requested.

*Rejection (item 1.3):* The Examiner has rejected claims 16, 18, 19, 22, 65 and 66 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,166,178 (the '178 patent). In particular, claim 16 is rejected as being anticipated by SEQ ID Nos: 5 and 225; claims 19 and 22 are rejected over the teachings of fragments of motifs T, 1 and 2; claim 18 is rejected as being 98.7% identical to SEQ ID No: 613 for example.

*Remarks:* All bases of this rejection are respectfully traversed. It is submitted that the disclosure of SEQ ID Nos: 5 and 225 are only entitled to a priority date of August 14, 1997, the filing date of one of the parent applications, U.S. Serial No. 08/911,312, and do not have support earlier than this date. Applicants own priority date to which the claims of the present application are entitled predates this August 14, 1997 date, and therefore, the Cech patent and its disclosure of the delta-182 is not prior art to the pending claims. Thus, the '178 patent does not anticipate claim 16 or new claim 70, and it is requested that the rejection be withdrawn.

With respect to the rejections of claims 19 and 22, this rejection is traversed. Claim 22 has been canceled, and claim 19 has been amended to recite specific fragments, which are not anticipated by the disclosure of the '178 patent. Specifically, the boundaries of these fragments are not disclosed or suggested by the '178 patent. At most, the priority document discloses the reference human telomerase. Although the description mentions various motifs of telomerase, including motif A, it does not identify or suggest the fragment of SEQ ID No: 26, called the  $\alpha$  exon. The  $\alpha$  exon encompasses amino acids 711-722 whereas motif A encompasses amino acids 708-720. Merely having some overlap between the motif and the exon does not rise to either anticipation of or suggest the precise fragment claimed.

Similarly the  $\beta$  exon, SEQ ID No: 28, is contained within the reference telomerase, but is not anticipated by or suggested by that sequence. In particular, SEQ ID No: 28 does not correspond to any motif described in the '178 patent.

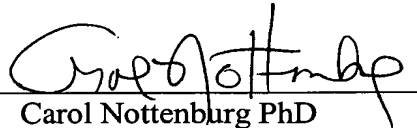
Applicants disagree that with the rejection of claim 18. The proteins of the '178 patent that are recited in the Office Action are either not splice variants or do not merit a priority earlier than that of the Applicants. In an effort to advance prosecution, however, claim 18 has been amended to delete the limitation for "variant" proteins. Therefore, all parts of the rejection have been overcome and the Examiner is requested to withdraw the rejection.

### *Conclusion*

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,

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